DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 30, 2014

lnnokas Yhtyma Oy
Ms. Tiina Kotipalo
Director of Quality and Regulatory Affairs
Vihikari 10
90440 Kempele
Finland

Re: K133810
Trade/Device Name: Vital Signs Monitor VC150
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: October 23, 2014
Received: October 27, 2014

Dear Ms. Kotipalo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133810

Device Name
VC150

Indications for Use *(Describe)*
The VC150 is intended to monitor a single patient's vital signs at the site of care or during intra-hospital transport.

The noninvasive oscillometric blood pressure parameter is intended for measurement of systolic, diastolic, and mean arterial blood pressure, as well as pulse rate, for adult, pediatric and neonatal patients.

The optional GE TruSignal pulse oximetry and accessories are indicated for continuous noninvasive monitoring of functional oxygen saturation (SpO2) and pulse rate, including monitoring during conditions of clinical patient motion or low perfusion, with adult, pediatric and neonatal patients.

The optional Masimo Rainbow SET® Pulse CO-oximetry and accessories are indicated for the continuous noninvasive monitoring of:
• functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate, during both no motion and motion conditions, and for patients who are well or poorly perfused (low perfusion) for adult, pediatric and neonatal patients,
• carboxyhemoglobin saturation (SpCO) for adult and pediatric patients,
• methemoglobin saturation (SpMet) for adult, pediatric and neonatal patients,
• total hemoglobin concentration (SpHb) for adult and pediatric patients, and/or
• respiratory rate (RRa) for adult and pediatric patients.

The optional Nellcor™ oximetry and accessories are indicated for the continuous, noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric, and neonatal patients during both motion and non-motion conditions, and for patients who are well or poorly perfused. The optional Oximax SPD™ Alert (SPD) feature is intended only for facility-use care of adults to detect patterns of desaturation indicative of repetitive reductions in airflow through the upper airway and into the lungs.

The optional Nellcor™ Respiration Rate parameter is intended for the continuous noninvasive monitoring of respiration rate in adult patients who are well perfused during non-motion conditions.

The optional Welch Allyn SureTemp Plus electronic thermometer is intended to measure oral, axillary, and rectal temperature of adult and pediatric patients. The optional Exergen TemporalScanner thermometer is intended for the intermittent measurement of human body temperature of patients of all ages.

A wireless network connection is provided to transmit clinical data into various hospital information systems. An optional remote alarm cable connection is intended to complement visual and audible alarms and not replace the need for the presence of a caregiver.

The portable device is designed for use in hospitals and hospital-type facilities. The VC150 can also be used in satellite areas or alternate care settings.

"Portable" refers to the ability of the VC150 to be easily moved by the caregiver, such as on a roll stand. The VC150 is not intended to be used for continuous monitoring during patient transport.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) number: K133810
Device Trade Name: VC150

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	Oct 30th, 2014
Submitter:	Innokas Yhtymä Oy Vihikari 10 90440 Kempele Finland
Primary Contact Person:	Tiina Kotipalo Director of Quality and Regulatory Affairs Innokas Yhtymä Oy Vihikari 10 90440 Kempele, Finland Phone: +358 44 5623 131 Fax: +358 8 562 3151 Email: tiina.kotipalo@innokasmedical.fi
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Device Trade Name:	VC150
Common/Usual Name:	Physiological or Vital Signs Monitor; Patient Monitor
Classification Names:	21 CFR 870.2300
Product Code:	MWI
Predicate Device(s):	K102426 CARESCAPE V100 Vital Signs Monitor K101680 Welch Allyn Spot Ultra Vital Signs and Welch Allyn Spot Vital Signs LXi

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K110028 Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and Accessories

K121806 Bedside Respiratory Patient Monitoring System

Device Description:

The VC150 is a portable vital signs monitor for use in hospitals and hospital-type facilities. It can be used also in satellite areas or alternate care settings. The monitor is used for adult, pediatric, and neonatal patients, one at a time. The battery-operated monitor offers non-invasive determination of blood pressure (systolic, diastolic, and mean arterial blood pressure), pulse rate, temperature, oxygen saturation, total hemoglobin, carboxyhemoglobin, methemoglobin, and respiration rate. The VC150 monitor includes features and measurement modules that are optional or configurable. The monitors can be equipped with the following parameters and technologies:

- NIBP and pulse rate: GE SuperSTAT or Classic (auscultatory) algorithms
- SpO2 and pulse rate: GE TruSignal, Nellcor OxiMax, or Masimo Rainbow SET
- Respiration rate: Nellcor OxiMax or Masimo Rainbow SET
- Hemoglobin (SpHb), Methemoglobin (SpMet), Oxygen Content (SpOC), and Carboxyhemoglobin (SpCO): Masimo Rainbow SET
- Temperature: Welch Allyn SureTemp Thermometer or Exergen Temporal Arterial Thermometer

The VC150 monitors include a wireless network connection. An integrated printer is optional. The VC150 has an 8.4-inch LCD panel with a touch screen and an alarm light integrated in the front bezel on top of the display. An optional cable connection is available to interface with a traditional nurse-call system for triggering remote alarms. A computer can be connected to the VC150 via a cable to retrieve electronic patient records stored on the device in PDF format.

Intended use:

The VC150 is intended to monitor a single patient's vital signs at the site of care or during intra-hospital transport.

The noninvasive oscillometric blood pressure parameter is intended for measurement of systolic, diastolic, and mean arterial blood pressure, as well as pulse rate, for adult, pediatric and

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neonatal patients.

The optional GE TruSignal pulse oximetry and accessories are indicated for continuous noninvasive monitoring of functional oxygen saturation (SpO_2) and pulse rate, including monitoring during conditions of clinical patient motion or low perfusion, with adult, pediatric and neonatal patients.

The optional Masimo Rainbow SET® Pulse CO-oximetry and accessories are indicated for the continuous noninvasive monitoring of:

- functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate, during both no motion and motion conditions, and for patients who are well or poorly perfused (low perfusion) for adult, pediatric and neonatal patients,
- carboxyhemoglobin saturation (SpCO) for adult and pediatric patients,
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- total hemoglobin concentration (SpHb) for adult and pediatric patients, and/or
- respiratory rate (RRa) for adult and pediatric patients.

The optional Nellcor™ oximetry and accessories are indicated for the continuous, noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric, and neonatal patients during both motion and non-motion conditions, and for patients who are well or poorly perfused. The optional Oximax SPD™ Alert (SPD) feature is intended only for facility-use care of adults to detect patterns of desaturation indicative of repetitive reductions in airflow through the upper airway and into the lungs.

The optional Nellcor™ Respiration Rate parameter is intended for the continuous, noninvasive monitoring of respiration rate in adult patients who are well perfused during non-motion conditions.

The optional Welch Allyn SureTemp Plus electronic thermometer

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A wireless network connection is provided to transmit clinical data into various hospital information systems. An optional remote alarm cable connection is intended to complement visual and audible alarms and not replace the need for the presence of a caregiver.

The portable device is designed for use in hospitals and hospital-type facilities. The VC150 can also be used in satellite areas or alternate care settings.

"Portable" refers to the ability of the VC150 to be easily moved by the caregiver, such as on a roll stand. The VC150 is not intended to be used for continuous monitoring during patient transport.

Technology: The VC150 employs the same fundamental scientific technology as its predicate devices. Conclusion from the substantial equivalence comparison submitted with this 510(k) demonstrate that VC150 monitor is as safe and effective and performs substantially equivalent as the following predicate devices:

- CARESCAPE V100 Vital Signs Monitor (K102426)
- Welch Allyn Spot Ultra Vital Signs and Welch Allyn Spot Vital Signs LXi (K101680)
- Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and Accessories (K110028)
- Bedside Respiratory Patient Monitoring System (K121806)

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The VC150 and its applications comply with voluntary standards as detailed in this premarket submission. The following quality assurance measures have been applied to the development of the system:

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- Establishment of requirements
- Risk management activities
- Design reviews
- Design verification testing
- System integration testing
- System verification and validation testing
- Performance testing
- Safety testing
- Usability testing

Summary of Clinical Tests:
The subject of this premarket submission, VC150, did not require clinical studies to support substantial equivalence.

Conclusion: The results of these activities demonstrate that the VC150 monitor is as safe, as effective, and performs as well as or better than the predicate devices.